PREMARKET NOTIFICATION 510(K) SUMMARY

JUL 26 2006

Company:

Altiva Corporation
9800 Suite i, Southern Pines Blvd
Charlotte, NC 28273
Telephone: 704/409-1754
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Company Contact: John Kapitan, Director Product Development, RA/QA

Date: May 24, 2006

Trade Name: ALTES™ Buttress Plating System

Common Name Anterior Lumbar Buttress System

Classification: Orthopedics, 888.3060, Class II

FDA Product Code : KWQ

Device Description:

The ALTES™ Anterior Buttress Plating System consists of plates and screws. The plate is shaped to conform to the anatomy of the anterior spine. The system features two screws which engage the vertebral body and prevent rotation. A unique locking mechanism of the screw prevents the plate and screws from releasing. The plates are available in three sizes: 20mm, 25mm, and 30mm. The screws are available in two diameters: 4.5mm and 5.0mm, and two lengths: 15mm and 20mm. The components of the ALTES™ Anterior Buttress Plating System are manufactured from titanium alloy and have a smooth anodized color-coded finish.

Intended Use:

The ALTES Anterior Buttress Plating System is intended for anterior intravertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent interverbral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

Predicate Device: Predicate device information is included.

Performance Data: Performance data were submitted to characterize the ALTES™ Anterior Buttress Plating System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Altiva Corporation
% Mr. John Kapitan
Director, RA/QA
9800 Southern Pines Blvd., Suite I
Charlotte, NC 28273

Re: K061482
Trade/Device Name: Altiva ALTES™ Buttress Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 24, 2006
Received: May 30, 2006

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

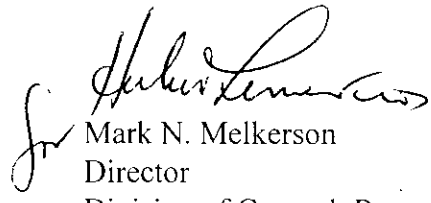
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K061482

Device Name: Altiva ALTES™ Buttress Plating System

Indications for Use:

The ALTES™ Buttress Plating System is intended for anterior intravertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent interverbral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

Prescription Use X or Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061482